The traceability system of medicines at Hospital Israelita Albert Einstein in Brazil

ABSTRACT

Focusing on patient safety, Albert Einstein Hospital (HIAE) has evaluated the entire cycle of drugs use and established three specific steps in the process where to implement electronic safety blocks: ordering, dispensing and administration. HIAE initiated the intra-hospital traceability project to monitor the receipt, distribution, dispensing, and administering of drugs. In a first phase, drugs were re-labeled in-house, and in a second phase, a supplier took up the challenge to print a bar code on the label of each unit of electrolyte ampoules in their production line. This allowed to include variable data such as batch number and expiry date. More suppliers were then invited to adopt the GS1 DataMatrix bar code. As a result, HIAE could reduce adverse drug events on dispensation and save costs by replacing in-house re-labeled drugs by industry two-dimensional codes ready identified labels.

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Introduction

According to studies by the American Hospital Association and another led by David Philips, both demonstrated by the IOM in its report To Err Is Human, 1999, each year 44,000 to 98,000 people die from medical errors and about 7,000 only by medication errors, inside or outside of hospitals. Additionally, it has been cited, that 2% of hospital admissions were subject to preventable adverse drug events, increasing the length of stay of 4.6 days with an additional cost of $ 4,700 per admission[1]. In statistics from the Centers for Disease Control and Prevention (CDC), this same report concluded that more people die from medical errors than from automobile accidents. Although more than 10 years have passed, these figures are alarming and makes us consider the quality of service nationwide. The costs of errors in estimation followed between 17 and 29 billion U.S. dollars annually. Medication errors in the most recent report of the IOM relied, in 2006, with an annual estimate of 400,000 adverse drug events, with consequent cost of 3.5 billion dollars annually[2].

In a study regarding the possible sources of medication errors, the ASHP, the American Association of Health System Pharmacists reported that 39% of errors occur at the time of prescription, 12% in transcription of medical orders, 11% in dispensing and 38% in medication administration[3]. While

these data are not specifically the national reality, are of vital importance as parameters for the improvements.

The data presented above are relatively recent, but the problem goes back much further. Already in the 1950s and 1960s, the Unit Dose Drug Delivery System (UDDDS) was developed in the USA as a means to reduce the alarming numbers of medication errors at that time. The UDDDS is a system through which the pharmacy dispenses the medication in the form which is ready for use, according to the dose ordered by the doctor, without the need of further manipulation[4]. Despite being recognized as the safest method of dispensing developed so far, the indicators still show that we have many weak points in the process and they deserve our full attention. But now, if we adopt the UDDDS as the best method of dispensing, what else do we need to accomplish?

1 Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human: building a safer health system. Washington, DC. National Academy Press; 1999.

2 Aspden P et al. Preventing Medication Errors: Quality Chasm Series. Washington, DC. National Academy Press; 2007.

3 ASHP Report. 2003 ASHP Leadership Conference on Pharmacy Practice Management. Executive Summary: Looking to the future: Leading and managing change. Am J Health-Syst Pharm 2004; 61(10): 1052-58.

4 American Society of Health-System Pharmacists [ASHP]. Best Practices for Health-System Pharmacy. Positions and Practice Standards of ASHP 1998-99. Bethesda, md: ASHP; 1998: p.134-5,139.

Patient safety at Hospital Israelita Albert Einstein (HIAE)

Focused on patient safety, we have evaluated the entire cycle of drugs use and decided to focus our actions on ordering, dispensing and administration. With the direct involvement of Pharmacy, we implemented an electronic ordering system and a safer logistics process from receipt of the products to their disposal.

These actions were aligned with the culture of quality and safety in HIAE which, even in the late 1990s, was seeking unprecedented certification from the Joint Commission Accreditation on Healthcare Organizations (JCAHO) outside the United States. The project allowed us to fulfill the Joint Commission's standard regarding the traceability of medicines.

> Joint Commission Accreditation on Healthcare Organizations Standard MM.05.01.17 (MMU.3.3 of Joint Commission International)
>
> The [organization] follows a process to retrieve recalled or discontinued medications.

The concept of quality of a Unit Dose System is unquestionable, but we see weak spots. With so many technological advances in our society, it is vital to take all reasonable and available means to safeguard the lives we serve daily. Our actions have been confirmed and reinforced with the publication of the IOM, which recommends the computerization and automation as means to prevent errors and adverse effects[5], in summary, a mechanism widely available and an efficient source of security.

The traceability project

The first step

To improve patient safety, HIAE initiated the intra-hospital traceability project,which had the purpose of monitoring the reception, distribution, dispensing, and administration of medication, and maintaining control over batch and expiry date of medicines in these processes.

Fig. 1 – EAN 13 code

Until then it was not possible to perform traceability because the drugs supplied by the manufacturers did not possess the minimum requirements for such control. Not all suppliers provided properly identified packages. Even if there was a bar code, it reported only what product it was (EAN13 code – Fig. 1), and usually in their secondary packaging. When it comes to dispensing hospital, it is imperative that full identification is carried out on primary packaging.

5 Institute of Medicine. Crossing the Quality Chasm. A New Health System for the 21st Century. Washington, DC. National Academy Press; 2001.

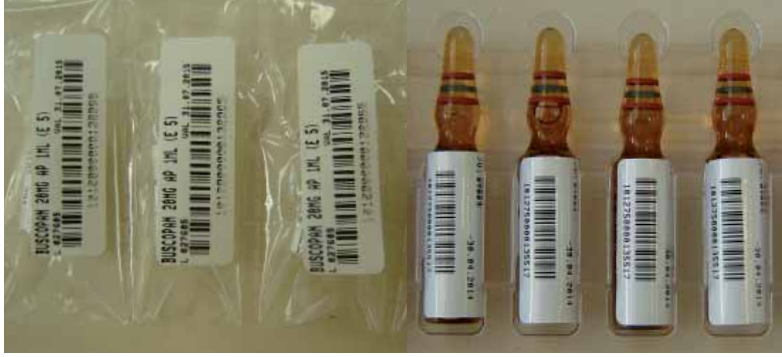


Fig. 2 – Re-labeled ampoules

To circumvent the problem and meet this demand, the alternative adopted was in re-labeling (re-identification) of medicines in all types of presentation and dosage forms, printing a bar code containing the product data, batch number and possibly expiry date, as well as that information in human readable format. For ampoules and vials it was a cumbersome solution (Fig. 2), but the situation became even more critical when dealing specifically with drugs in solid dosage forms (e.g. tablets, capsules, etc.)[6]. To have this information on each unit of consumption, we had to cut original blister packs and individually overwrap each unit. To facilitate this process, HIAE invested in a table top machine for unit dose repackaging (Fig. 3). In the Brazilian market, the sale of drugs in bulk is practically nonexistent, which makes this activity more costly and creates too much waste, like cartridges, blister packs and package inserts. For this practice, later, with the publication of RDC 67/2007 ANVISA (Resolution of Directive College)[7], in the repackaging process through table top machines, the validity of the drug should be reduced to 25% of its original remaining time. This situation remains until today.

In 2005, for the attendance of 460 beds, emergency care and two outpatient units (Paraisópolis Alphaville), HIAE repackaged approximately 80,000 oral solids and relabeled about 250,000 ampoules or vials per month.

6 Cina J, et al. Implementing a bar code repackaging center: a case study of the process from the department of pharmacy services Brigham & Women's Hospital in Boston. Pharm Purchasing Products 2004; 1:10–11.

7 BRASIL. Agência Nacional de Vigilância Sanitária. RDC nº67, de 1º de outubro de 2007. Regulamento Técnico sobre Boas Práticas de Manipulação de Preparações Magistrais e Oficinais para Uso Humano em farmácias. Diário Oficial da República Federativa do Brasil, Poder Executivo, Brasilia, DF, 8 de outubro de 2007, Seção 1. Available at <http://www.anvisa.gov.br/legis/resol/2007/rdc/67_rdc_anexo.pdf> accessed on February 3, 2011.

Risks

The activity of re-labeling is a critical step as it adds cost - namely the high cost of manpower - and risk - the risk of having of incomplete or inaccurate information. To prevent these errors, a policy and post-labeling quality control need to be developed[8].

We can also see errors when receiving medications. Right now, with lot control in the internal distribution of products, the lot information and expiry date should be typed into the system. With this, we run up against the risk of copy error, compromising the ability of traceability of data over the period of medication use.

Furthermore, we have to pay attention to the printing quality of labels, because faded codes can not be read and the whole chain is compromised. Therefore, it is essential to have an effective program of preventive maintenance on printers, labels and acquisition of appropriate print film, so that it will not fade out during handling or with liquids used in aseptic processes.

The ideal solution

Through our participation in the GS1 Healthcare Brasil user group, we identified a supplier that accepted the challenge of applying the two-dimensional GS1 RSS-14 code (currently called DataBar – Fig. 4) on the label of each unit of electrolyte ampoules in their production line. In this format of higher capacity, you can enter variable data such as batch and expiry date on their information content. Later in 2008, new partners have joined the programme and followed the international guidelines that required the use of GS1 DataMatrix code (Figs. 5 and 6). With this new two-dimensional code with variable content, the re-labeling of all products was no longer needed, and a safer receiving process was established. Upon reading the code, the system automatically imports the data from batch and expiry date, thus eliminating the possibility of error in the inventory system data record. In a survey on the current status of hospital pharmacies by the American Society of Health-System Pharmacists (ASHP)[9], Zellmer[10] indicated the need for manufacturers to supply pre-packed drugs in already bar coded individualized doses to increase security and save costs. This is in line with the group's studies of GS1 Brasil.

Fig. 4 - GS1 DataBar Stacked Omnidirectional

Fig. 5 – GS1 DataMatrix

Fig. 6 – Ampoules with GS1 DataMatrix

A considerable challenge for the national pharmaceutical industry still remains as to the application of bar code on blister packs of oral solids (Fig. 7). It is intended that, once cut (through perforated blister packs), all units have the identification required for full traceability, without re-packing need at hospitals that perform the Unit Dose dispensing process.

By December 2010, other suppliers joined the programme and HIAE expanded its services to about 600 beds, emergency care and four other outpatient units (Paraisópolis, Alphaville, Perdizes-Higienópolis and Ibirapuera). About 180,000 oral solids had to be re-packaged per month and some 250,000 ampoules or vials re-labeled per month. Another 120,000 units of ampoules and vials do not have to be re-labeled anymore as they already carry the GS1 DataMatrix code.

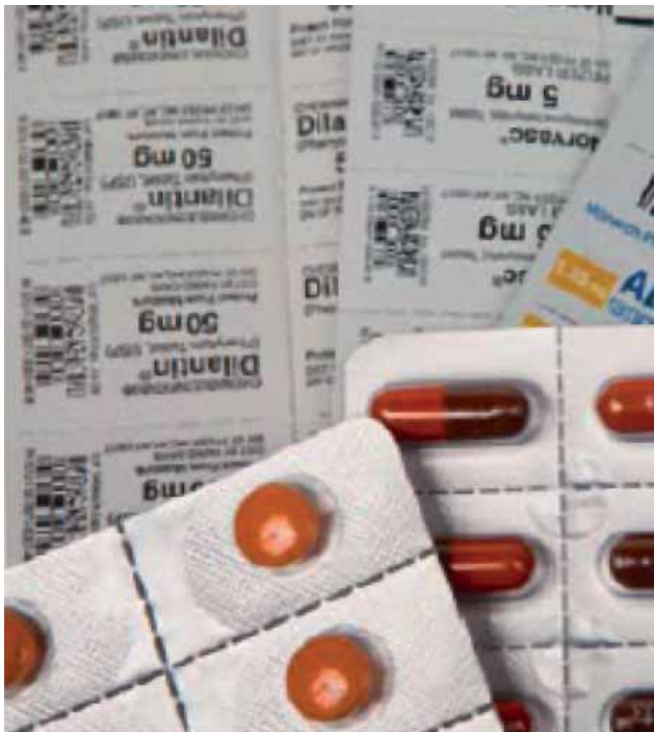
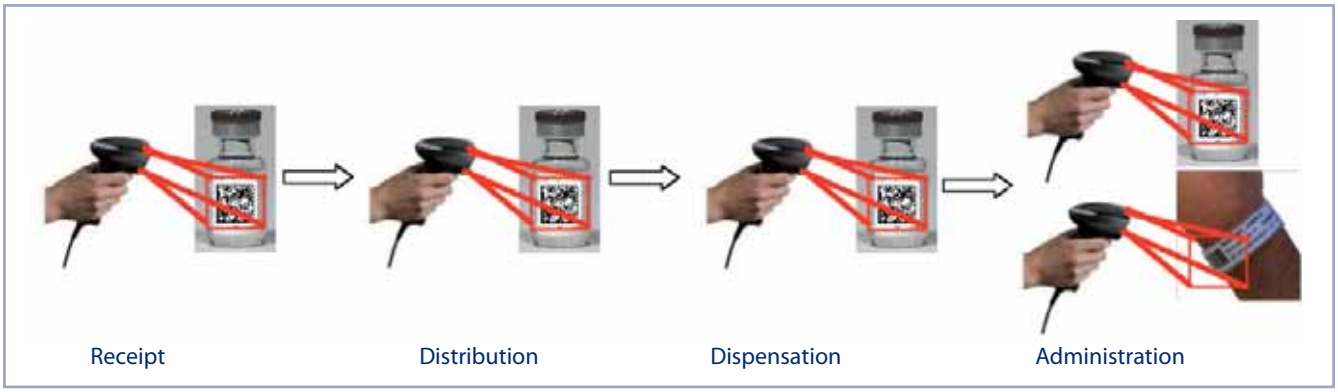


Fig. 7 – Bar code on blister packs

8 Cina J, et al. Medication errors in pharmacy-based bar-code-repackaging center. Am J Health –Syst Pharm 2006; 63(2): 165–168.

9 Pedersen CA, Gumpper KF. ASHP national survey on informatics: Assessment of the adoption and use of pharmacy informatics in U.S. hospitals – 2007. Am J Health-Syst Pharm 2008; 65(23): 2244-2264.

10 Zellmer W. The current state of hospital pharmacy. Am J Health-Syst Pharm 2009; 66(10): 895.



Software assessment

To adopt the standards, all systems used in the hospital logistics had to be customised in order to allow the code information recovery.

In the process of reading the code, the system should recognize the character FNC1, relevant Application Identifiers (AI) and save it. In the most basic example, the system must understand that specific product GTIN14 (AI 01) corresponds to a unique product in its internal inventory. It must therefore record the batch information and expiry date, and make a full identification of the medicine in the internal supply chain.

Though seemingly complex, it is not. GS1 offered thorough support so that the necessary adjustments were easily understood.

Bedside check medication administration

The solution will also directly impact medication administration, one of the most critical and sensitive stages for error as shown in the ASHP statistics. In 2011, HIAE will adopt an electronic checking system of medication administration at bedside. In this process, the nursing staff reads the patient id code and the bar code of the medicine dispensed by the pharmacy, confirming the drug. In the absence of a bar code on the primary packaging of the product, this process becomes impractical.

Much has been discussed and published about the automation of this process and the main objective is to achieve the five well-known rights: right patient, right drug, right route, right time and right dose. This particular issue has been further studied and the number 5 now comes to 9[11], where we perceive that the automated process allows most of them to be covered with the deployment of technology: electronic checking allows right patient, right drug, right dose, right time, right registration (documentation), right of refusal and right justification. Patient education and right route still remain inherent to the professional involved.

11 Elliott, M. and Liu, Y. The nine rights of medication administration: an overview. British Journal of Nursing 2010. 19(5), p.300-305.

Additional security checks

According to James Reason[12], the errors are not confined to a few individuals. Even the most qualified professionals are subject to failure. Often circumstances lead to errors. The mere proposal of the use of bar code makes use of medications safer leveraging technology.

Wherever possible, additional security checks during the process should be considered, The Swiss cheese model of Reason makes it very clear when failures momentarily align and potential errors become real (Fig. 8).

Legislation

Traceability of medicines has also entered the merit of norms of the National Agency for Sanitary Surveillance (ANVISA), the national body responsible for regulating the health sector in Brazil[13,14,15,16,17,18].

12 Reason J. Human Error: Models and Management, BMJ 2000, 320: p 768–770.

13 BRASIL. Agência Nacional de Vigilância Sanitária. Consulta Pública nº 8, de 4 de março de 2008. Diário Oficial [da República Federativa do Brasil], Brasília, DF, 5 de março de 2008, Seção 1. Available at <http://www4.anvisa.gov.br/base/visadoc/CP/CP%5B21581-1-0%5D.PDF> accessed on February 3, 2011.

14 BRASIL. Lei nº 11.903, de 14 de janeiro de 2009. Dispõe sobre o rastreamento e do consumo de medicamentos por meio de tecnologia de captura, armazenamento e transmissão eletrônica de dados. Diário Oficial [da República Federativa do Brasil], Brasília, DF, n. 10, 15 de janeiro de 2009, Seção 1, p1.

15 BRASIL. Agência Nacional de Vigilância Sanitária. RDC Nº 59, de 24 de novembro de 2009. Dispõe sobre a implantação do Sistema Nacional de Controle de Medicamentos e definição dos mecanismos para rastreamento de medicamentos, por meio de tecnologia de captura, armazenamento e transmissão eletrônica de dados e dá outras providências. Diário Oficial [da República Federativa do Brasil], Brasília, DF, 25 de novembro de 2009, Seção 1, p 58.

16 BRASIL. Agência Nacional de Vigilância Sanitária. Instrução Normativa n°1, de 13 de janeiro de 2010.Regulamenta a Resolução RDC n° 59, de 24 de novembro de 2009, que dispõe sobre a implantação do Sistema Nacional de Controle de Medicamentos, com vistas ao regramento da produção e o controle da distribuição das etiquetas de segurança para o Sistema de Rastreamento de Medicamentos e dá outras providências. Diário Oficial [da República Federativa do Brasil], Brasília, DF, 14 de janeiro de 2010, Seção 1, p 60.

17 BRASIL. Agência Nacional de Vigilância Sanitária. Instrução Normativa n°8, de 15 de junho de 2010. Dá nova redação ao caput e revoga os §§1º, 2º, 3º e 4º do art. 9º da Instrução Normativa nº 1, de 13 de janeiro de 2010 [da República Federativa do Brasil], Brasília, DF, 17 de junho de 2010, Seção 1, p 39.

18 BRASIL. Agência Nacional de Vigilância Sanitária. Instrução Normativa n°11, de 29 de outubro de 2010. Dispõe sobre a tecnologia, a produção, o fornecimento e o controle da distribuição das etiquetas auto-adesivas de segurança para o Sistema de Rastreamento de Medicamentos e dá outras providências. [da República Federativa do Brasil], Brasília, DF, 3 de novembro de 2010, Seção 1, p 17.

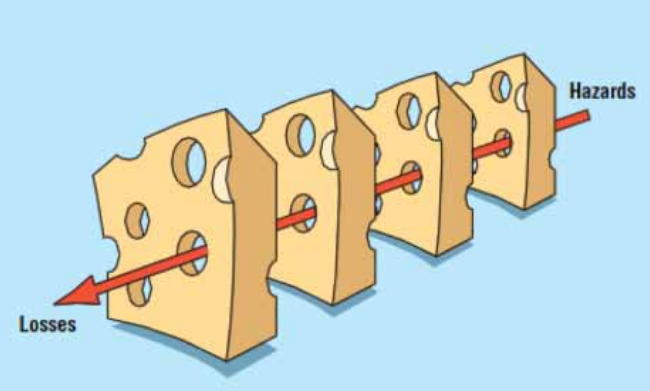


Fig. 8 – The Swiss cheese model of reason

Concerned about the continued practice of drug counterfeiting and theft of cargo, ANVISA published specific legislation to put a control in this matter. On January 14, 2009 the law 11,903 was published, determining the creation of the national traceability system of drugs from production to consumption through electronic means.

Subsequently, it was published on November 25, 2009, the RDC 59 (Resolution of Directive College), providing the establishment of the National System of Control of Drugs and the mechanisms for tracking medicines electronically. The resolution clarifies that the drugs should be identified with the DataMatrix code in its secondary packaging. Without this, the identification must be on the primary packaging. The law does not meet the security needs of traceability inside the hospital, however, demonstrates an important breakthrough for the security of the population that uses drugs in retail pharmacies.

Many normative statements were published (#1 on January 14, 2010, #8 on June 17, 2010 and #11 on November 3, 2010), detailing the specific mechanism for tracking and control of medicines. The normative determine the use of GS1 DataMatrix as a tool, which shall have minimum amount of information, among which the GTIN, lot, expiry date and IUM (unique identifier of medicine - following serialization standard of GS1), which is directly linked to product registration in the ANVISA and CNPJ (Juridical Person National Register/Tax Number) of the receiving company.

Results achieved through the implementation of traceability using two-dimensional bar codes at HIAE.

The process is safer based on the GS1 DataMatrix previously printed on the label on the primary packaging of pharmaceutical product (smallest unit of consumption).

- Agility in the dispensing process, with online inventory decrement
- Conference of the item dispensed as ordered
- History of the batch of the drug from the receipt to the time it is used by patients (TRACEABILITY inside the hospital)
- Item History, from manufacturing to its consumption (complete TRACEABILITY outside and inside the hospital)
- Guarantee the dispensing drugs in condition of use, with lots being blocked from dispensing which may have been recalled or are expired
- History of the batch sent to each sector
- Agility in localizing products banned for recall
- Electronic bedside check of medication administration, according to the order and ensuring control over 7 of 9 rights proposed
- Important tool for obtaining quality certifications
- Reduced about 330 hours of manpower costs at the relabeling activity

Final thoughts

On several occasions those responsible for hospital pharmacies face many obstacles that hinder the development of traceability projects and it is not unusual that financial reasons or lack of management support take place. It is noteworthy that, compared to the costs generated by the error and the time of manpower spent on tasks that do not add any value, but offer more risk, are factors that easily demonstrate the rapid return on investment.

Additionally, attention to the legislation is the focal point of the moment. With the progress of the national project and the encouragement of other institutions at the national level, we hope to elevate Healthcare to a higher level in quality. Currently attention is focused on legislation to guarantee genuine products and of legal origin; however, it is expect that in the future we will have regulation for the primary packaging based on the GS1 DataMatrix identification.

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About Hospital Israelita Albert Einstein

In 1955, a group of idealists from the Jewish community of São Paulo founded Sociedade Beneficente Israelita Brasileira Albert Einstein (SBIBAE), based upon four traditional Jewish principles:

- Good Deeds (Mitzvá)
- Health, Healing (Refuá)
- Education (Chinuch)
- Solidarity, Justice (Tsedaká)

Over half a century later, SBIBAE has become a great and modern institution, governed by high quality standards and in tune with the most advanced technologies available. SBIBAE is aligned to modernization and focused on health above all things. Daring innovation and persistence in the pursuit for quality are the Society's distinguished attributes.

Hospital Israelita Albert Einstein (HIAE), founded in 1971, is a patient-oriented institution and therefore prepared to offer, with attention and respect, unique and innovative services: from preventive medicine to complete rehabilitation.

Several initiatives are in place to prevent, eliminate or minimize risks and flaws in our service. Our procedures are guided by the American Institute of Medicine (AIOM), Joint Commission International (JCI), Institute of Health Care Improvement (IHI), the World Health Organization, and the Einstein Quality System.

HIAE is one of the most reputable organizations in Latin America. In 1999, it was the first hospital outside the USA to be accredited by the Joint Commission International – the international arm of The Joint Commission.